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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No. ACS 50716
First Inventor or Application Identifier Lilip Lau
Title Stent Delivery System
Express Mail Label No. EL045597362US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ * Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Specification [Total Pages 14]
(preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 3]
4. Oath or Declaration [Total Pages 8]
 - a. ☐ Newly executed (original or copy)
 - b. ☒ Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
 - i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

ADDRESS TO:

Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

ACCOMPANYING APPLICATION PARTS

7. ☐ Assignment Papers (cover sheet & document(s))
8. ☐ 37 C.F.R. § 3.73(b) Statement of Power of Attorney
(when there is an assignee)
9. ☐ English Translation Document (if applicable)
10. ☐ Information Disclosure Statement (IDS)/PTO-1449 [Copies of IDS Citations]
11. ☒ Preliminary Amendment
12. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. ☐ * Small Entity Statement(s) [Statement filed in prior application, Status still proper and desired (PTO/SB/09-12)]
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. ☐ Other:

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

☐ Continuation ☒ Divisional ☐ Continuation-in-part (CIP) of prior application No. 09 / 136,982
Prior application information: Examiner R. Stright Group / Art Unit: 3734

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of)	Examiner: W. Lewis
)	
Inventors: Lilip Lau, William M. Hartigan)	Art Unit 3734
)	
Serial Number: Divisional of USSN)	
09/136,982)	Docket No. ACS 50716
)	
Filed: Concurrently)	
)	
For: STENT DELIVERY SYSTEM)	May 14, 1999

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Preliminary Amendment is being filed concurrently with a divisional application under 37 C.F.R. § 1.53(b). This application is a divisional of U. S. Serial No. 09/136,982 filed August 20, 1998, which is a divisional application of U.S. Serial No. 09/119,344 filed July 20, 1998, which is a divisional application of U.S. Serial No. 08/630,528, which issued at U.S. Patent No. 5,782,855 on July 21, 1998, which was a divisional application of U.S. Serial No. 08/085,959, which issued as U.S. Patent No. 5,507,768 on April 16, 1996, which was a continuation-in-part application of U.S. Serial No. 07/647,464 filed January 28, 1991, now abandoned.

IN THE SPECIFICATION

On page 1, delete the sentence spanning lines 5-7 and insert the following:

--This application is a divisional of U.S. Serial No. 09/119,344 filed July 20, 1998, which

is a divisional of U.S. Serial No. 08/630,528 filed April 10, 1996, now U.S. Patent No. 5,782,855, which is a divisional of U.S. Serial No. 08/085,959 filed July 6, 1993, now U.S. Patent No. 5,507,768, which is a continuation-in-part application of U.S. Serial No. 07/647,464 filed January 28, 1991, now abandoned.--

At page 4, line 25 delete "a distal portion which tapers down,".

At page 4, line 30 through page 5, line 2, delete all of the material beginning with "The" and ending with "thereof."

At page 4, line 30, after "." insert the following sentence: --The delivery system also includes an intravascular catheter slidably disposed within the inner lumen of the delivery sheath, the catheter having an expandable member on the distal extremity thereof, such as an inflatable balloon, which is adapted to receive an expandable stent on the exterior thereof--.

At page 5, lines 21-25, delete the sentence beginning with "The" and ending with "catheter."

At page 5, lines 33-37, delete "is first inserted through an elastic cone by threading the guidewire into the smaller and out the larger of the two apertures which comprise the cone. Then the guidewire".

At page 6, line 3, after the word "within", insert --the inner lumen of--.

At page 6, lines 12-17, delete all of the material beginning with "The" and ending with "vessels."

At page 6, lines 20-21, delete “through a guiding catheter which extends from outside the patient to the ostium of the desired coronary artery,”.

At page 6, line 19, after the word “preferably”, insert --over a guide wire which extends from outside the patient to the ostium of the desired coronary artery,--.

At page 6, lines 32-34, delete the sentence beginning with “As” and ending with “catheter.”

At page 7, line 9, delete the first occurrence of the word “the” and insert --
They are removed over the guide wire until the proximal guide wire port on the sheath and/or the catheter exits the proximal end of the guiding catheter, the--.

At page 7, line 11, after the “.” insert --The sheath and the intravascular catheter are pulled proximally out of the proximal end of the guiding catheter a sufficient distance to expose the guide wire--.

At page 7, lines 30-31, delete “and elastic cone of the stent delivery system”.

At page 8, lines 7-9, delete “and the location of the elastic cone prior to the relative axial position adjustment of the delivery sheath and intravascular catheter”.

At page 8, lines 12-15, delete “and the location of the elastic cone after the relative axial position adjustment of the delivery sheath and intravascular catheter”.

At page 8, line 34, delete “outer” and insert --inner--.

At page 9, lines 6-12, delete all of the material beginning with “During” and ending with “16.”

At page 9, line 15, delete “outer” and insert --inner--.

At page 9, lines 16-20, delete the sentence beginning with “The” and ending with “sheath.”

At page 9, lines 21-26, delete all of the material beginning with “In” and ending with “catheter 12.”

At page 10, line 32 through page 11, line 2, delete all of the material beginning with “As” and ending with “catheter 12.”

At page 11, lines 13-16, delete all of the material beginning with “is” and ending with “guidewire 26”.

At page 11, line 22, delete “outer” and insert --inner--.

At page 11, lines 28-31, delete the sentence beginning with “The” and ending with “cone 58.”

At page 11, line 35 through page 12, line 4, delete all of the material beginning with the first full sentence starting with the word “The” and ending with “vasculature.”

At page 12, lines 12-14, delete the sentence beginning with “The” and ending with “Fig. 1.”

IN THE CLAIMS:

Prior to examination of the application, please cancel claim 1.

Please add the following claims:

36. An intravascular stent delivery assembly, comprising:

a. a catheter having:

i. a proximal end and a distal end;

ii. a distal port at the distal end;

5 iii. a proximal port spaced a relatively short distance from the
distal end and a relatively long distance from the proximal end;

 iv. a passageway for a guide wire extending between the distal
port and the proximal port; and

v. an expandable member for expanding a stent; and

10 b. a stent disposed about the expandable member.

37. The assembly of claim 36, wherein the stent is mounted on the expandable
member.

38. The assembly of claim 36, wherein the stent is longitudinally flexible and
expandable and comprises a plurality of cylindrical elements which are independently

expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis.

39. The assembly of claim 36, wherein the expandable member comprises a balloon.

40. The assembly of claim 36, wherein the catheter has an inflation passageway.

41. The assembly of claim 40, wherein the inflation passageway is in fluid communication with the balloon.

42. The assembly of claim 36, further comprising a sheath having a passageway for receiving the catheter.

43. The assembly of claim 42, wherein the sheath has a first port at a distal end of the sheath and a second port spaced distally of the proximal end of the sheath.

44. The assembly of claim 43, wherein a slit in the sheath extends distally from the second port so that the guide wire can be pulled through the slit during catheter exchanges.

45. The assembly of claim 36, wherein a slit in the catheter extends distally from the proximal port so that the guide wire can be pulled through the slit during catheter exchanges.

46. The assembly of claim 38, wherein the cylindrical elements of the stent are out of phase.

47. An intravascular stent delivery assembly, comprising:

- a. a catheter having
 - i. a proximal end and a distal end;
 - ii. a distal guide wire port at the distal end;
 - iii. a proximal guide wire port spaced a relatively short distance from the distal end and a relatively long distance from the proximal end;
 - iv. a passageway for a guide wire extending between the distal guide wire port and the proximal guide wire port; and
 - v. an expandable member for expanding a stent; and

b. a longitudinally flexible and expandable stent disposed about the expandable member of the catheter, the stent comprising a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis.

48. The assembly of claim 47, wherein the stent is mounted on the expandable member.

49. The assembly of claim 47, wherein the expandable member comprises a balloon.

50. The assembly of claim 49, wherein the catheter has an inflation passageway.

51. The assembly of claim 50, wherein the inflation passageway is in fluid communication with the balloon.

52. The assembly of claim 47, further comprising a sheath having a passageway for receiving the catheter.

53. The assembly of claim 52, wherein the sheath has a first port at a distal end of the sheath and a second port spaced distally of the proximal end of the sheath.

54. The assembly of claim 53, wherein a slit in the sheath extends distally from the second port so that the guide wire can be pulled through the slit during catheter exchanges.

55. The assembly of claim 47, wherein a slit in the catheter extends distally from the proximal port so that the guide wire can be pulled through the slit during catheter exchanges.

56. The assembly of claim 47, wherein the cylindrical elements of the stent are out of phase.

57. An intravascular stent delivery assembly comprising:

a. a catheter having

i. a proximal end and a distal end;

ii. a distal port at the distal end;

iii. a proximal port spaced a relatively short distance from the

distal end and a relatively long distance from the proximal end;

iv. a passageway for a guide wire extending between the distal port and the proximal port;

v. a long relatively stiff proximal section;

vi. a short relatively flexible distal section; and

vii. an expandable member for expanding a stent; and

b. a stent disposed about the expandable member.

58. The assembly of claim 57, wherein the stent is mounted on the expandable member.

59. The assembly of claim 57, wherein the stent is longitudinally flexible and expandable and comprises a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis.

60. The assembly of claim 57, wherein the expandable member comprises a balloon.

61. The assembly of claim 60, wherein the catheter has an inflation passageway.

62. The assembly of claim 61, wherein the inflation passageway is in fluid communication with the balloon.

63. The assembly of claim 57, further comprising a sheath having a passageway for receiving the catheter.

64. The assembly of claim 63, wherein the sheath has a first port at a distal end of the sheath and a second port spaced distally of the proximal end of the sheath.

65. The assembly of claim 64, wherein a slit in the sheath extends distally from the second port so that the guide wire can be pulled through the slit during catheter exchanges.

66. The assembly of claim 57, wherein a slit in the catheter extends distally from the proximal port so that the guide wire can be pulled through the slit during catheter exchanges.

67. The assembly of claim 59, wherein the cylindrical elements of the stent are out of phase.

68. The assembly of claim 57, wherein a stiffening mandrel is disposed within at least the proximal section of the catheter.

69. An intravascular stent delivery assembly, comprising:

a. a catheter having

i. a proximal end and a distal end;

ii. a distal guide wire port at the distal end;

5 iii. a proximal guide wire port spaced a relatively short distance from the distal end and a relatively long distance from the proximal end;

 iv. a passageway for a guide wire extending between the distal guide wire port and the proximal guide wire port;

v. a long relatively stiff proximal section;

10 vi. a short relatively flexible distal section; and

 vii. an expandable member for expanding a sent; and

 b. a longitudinally flexible and expandable stent disposed about the expandable member of the catheter, the stent comprising a plurality of cylindrical elements which are independently expandable in the radial direction and which are
15 interconnected so as to be generally aligned on a common longitudinal axis.

70. The assembly of claim 69, wherein the stent is mounted on the expandable member.

71. The assembly of claim 69, wherein the expandable member comprises a balloon.

72. The assembly of claim 71, wherein the catheter has an inflation passageway.

73. The assembly of claim 72, wherein the inflation passageway is in fluid communication with the balloon.

74. The assembly of claim 69, further comprising a sheath having a passageway for receiving the catheter.

75. The assembly of claim 74, wherein the sheath has a first port at a distal end of the sheath and a second port spaced distally of the proximal end of the sheath.

76. The assembly of claim 75, wherein a slit in the sheath extends distally from the second port so that the guide wire can be pulled through the slit during catheter exchanges.

77. The assembly of claim 69, wherein a slit in the catheter extends distally from the proximal port so that the guide wire can be pulled through the slit during catheter exchanges.

78. The assembly of claim 69, wherein the cylindrical elements of the stent are out of phase.

79. The assembly of claim 69, wherein a stiffening mandrel is disposed within at least the proximal section of the catheter.

REMARKS

This application is a divisional of U.S. Serial 09/136,982 filed August 20, 1998, which is a divisional application of U.S. Serial No. 09/119,344 filed July 20, 1998, which is a divisional application of U.S. Serial No. 08/630,528, which issued at U.S. Patent No. 5,782,855 on July 21, 1998, which was a divisional application of U.S. Serial No. 08/085,959, which issued as U.S. Patent No. 5,507,768 on April 16, 1996, which was a continuation-in-part application of U.S. Serial No. 07/647,464 filed January 28, 1991, now abandoned.

Claims 36-79 are now pending in the application. Claim 1 has been canceled.

The subject matter of the claims is fully supported by the originally filed application, namely, U.S. Serial No. 07/647,464 filed January 28, 1991, in which inventors Lilip Lau and William Hartigan were the named inventors. Subsequently, a continuation-in-part application (U.S. Serial No. 08/085,959) was filed in which a third inventor, Farhad Khosravi, was added as an inventor. Since the subject matter of the present claims is supported by the original application naming Messrs. Lau and Hartigan as inventors, Mr. Khosravi is not a named inventor on the present application. It is believed that no correction of inventorship is necessary under 37 C.F.R. § 1.48(b), however, if the Examiner feels inventorship correction is required, applicants will file the necessary petition to correct inventorship.

Since the subject matter of the claims is fully supported by the originally filed application U.S. Serial No. 07,647,464, the specification has been amended to delete the new matter presented in U.S. Serial No. 08/085,959 filed July 6, 1993. The new matter which was the subject of the continuation-in-part application related primarily to an elastic nose cone attached to the distal end of catheter. The nose cone invention is not part of the presently claimed invention. With the present amendments to the specification, it is believed that the specification (excluding the Abstract and claims) is substantially the same as the originally filed U.S. Serial No. 07/647,464 filed January 28, 1991.

It also is noted that the drawing figures filed in this application are being substituted with the drawing figures filed in the originally filed application (U.S. Serial No. 07/647,464). The drawing figures being replaced depict the nose cone (e.g., Figs. 1 and 2) which again is not part of the claimed invention.

It is believed that the pending claims are patentable over the art and it is respectfully requested that early allowance be granted.

Respectfully submitted,

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Application of

Lilip Lau, William M. Hartigan,
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for

UNITED STATES LETTERS PATENT

on

STENT DELIVERY SYSTEM

Drawings: Three Sheets
Atty Docket: ACS-34511

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STENT DELIVERY SYSTEM

RELATED APPLICATION

5 This application is a continuation-in-part of co-pending U.S. patent application Serial No. 07/647,464, filed January 28, 1991.

BACKGROUND OF THE INVENTION

10 This invention relates to devices for the treatment of heart disease and particularly to endo-arterial prosthesis, which are commonly called stents.

15 Several interventional treatment modalities are presently used for heart disease including balloon and laser angioplasty, atherectomy and by-pass surgery.

20 In typical balloon angioplasty procedures, a guiding catheter having a preformed distal tip is percutaneously introduced through the femoral artery into the cardiovascular system of a patient in a conventional Seldinger technique and advanced within the cardiovascular system until the distal tip of the guiding catheter is seated in the ostium of a desired coronary artery. A guidewire is positioned within an inner lumen of a dilatation catheter and then both are advanced through the
25 guiding catheter to the distal end thereof. The guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses a lesion to be dilated, then the dilatation catheter having an inflatable balloon
30 on the distal portion thereof is advanced into the patient's coronary anatomy over the previously introduced guidewire until the balloon of the dilatation catheter is properly positioned across the lesion. Once in position
35 across the lesion, the balloon which is made of relatively inelastic materials, is inflated to a predetermined size with radiopaque liquid at relatively high pressure (e.g.,

greater than 4 atmospheres) to compress the arteriosclerotic plaque of the lesion against the inside of the artery wall and to otherwise expand the inner lumen of the artery. The balloon is then deflated so that blood flow can be resumed through the dilated artery and the dilatation catheter can be removed therefrom. Further details of dilatation catheters, guidewires, and devices associated therewith for angioplasty procedures can be found in U.S. Patent 4,323,071 (Simpson-Robert); U.S. Patent 4,439,185 (Lindquist); U.S. Patent 4,516,972 (Samson); U.S. Patent 4,538,622 (Samson, et al.); U.S. Patent 4,554,929 (Samson, et al.); U.S. Patent 4,616,652 (Simpson); U.S. Patent 4,638,805 (Powell); and U.S. Patent 4,748,982 (Horzewski, et al.) which are hereby incorporated herein in their entirety by reference thereto.

A major problem which can occur during balloon angioplasty procedures is the formation of intimal flaps which can collapse and occlude the artery when the balloon is deflated at the end of the angioplasty procedure. Another major problem characteristic of balloon angioplasty procedures is the large number of patients which are subject to restenosis in the treated artery. In the case of restenosis, the treated artery may again be subjected to balloon angioplasty or to other treatments such as by-pass surgery, if additional balloon angioplasty procedures are not warranted. However, in the event of a partial or total occlusion of a coronary artery by the collapse of a dissected arterial lining after the balloon is deflated, the patient is put in an extremely dangerous situation requiring immediate medical attention, particularly in the coronary arteries.

A major focus of recent development work in the treatment of heart disease has been directed to endoprosthetic devices called stents. Stents are generally cylindrically shaped intravascular devices which are placed within a damaged artery to hold it open. The device can be used to prevent restenosis and to maintain the patency of

blood vessel immediately after intravascular treatments. In some circumstances, they can also be used as the primary treatment device where they are expanded to dilate a stenosis and then left in place.

5 However, the rapid and effective delivery of a stent to the desire location within the patient's vasculature has been found to be difficult, particularly in those situations in which an intimal flap has occluded an artery. Attempts to advance a stent into regions of
10 coronary arteries occluded by dissected arterial linings have not been very successful.

15 The two basic methods and systems have been developed for delivering stents to desired locations within body lumens. One method and system involves compressing or otherwise reducing the diameter of an expandable stent, disposing the compressed stent within a lumen provided in the distal end of a tubular catheter, advancing the catheter through the patient's vasculature until the distal end of the catheter is immediately adjacent to the desired
20 vascular location and then pushing the stent out the distal end of the catheter into the desired location. Once out of the catheter, the compressed stent expands or is expanded to thereby hold open the artery or other body lumen into which it is placed.

25 Another method and system involves disposing a compressed or otherwise small diameter stent about an expandable member such as a balloon on the distal end of a catheter, advancing the catheter through the patient's vascular system until the sent is in the desired location
30 within a blood vessel and then expanding the expandable member on the catheter to expand the stent within the blood vessel. The expanded expandable member is then contracted and the catheter withdrawn, leaving the expanded stent within the blood vessel, holding open the passageway
35 thereof.

The following references illustrate various types of stents and stent delivery systems. The list is meant to be exemplary, not exhaustive on the subject.

U.S. 3,868,956	U.S. 4,733,665	U.S. 4,856,516
U.S. 4,503,569	U.S. 4,760,849	U.S. 4,878,906
U.S. 4,512,338	U.S. 4,762,128	U.S. 4,886,062
U.S. 4,553,545	U.S. 4,768,507	U.S. 4,907,336
U.S. 4,560,374	U.S. 4,795,458	U.S. 4,913,141
U.S. 4,655,771	U.S. 4,800,882	U.S. 4,923,464
U.S. 4,665,918	U.S. 4,830,003	U.S. 4,950,227

What has been needed and heretofore unavailable is a stent delivery system which can be quickly and easily used in a wide variety of situations and particularly in emergency situations where a dissected arterial lining has collapsed and has occluded the flow of blood to a vital organ. The present invention satisfies this need.

SUMMARY OF THE INVENTION

This invention is directed to an improved stent delivery system which can quickly and easily position a stent into an occluded region of a blood vessel.

The stent delivery system of the invention includes an elongated sheath having an inner lumen extending therein, a distal portion which tapers down, a first port in its distal end which is adapted to receive a guidewire and a second port spaced proximally from the distal end of the delivery sheath which is also adapted to receive a guidewire, both of the ports being in fluid communication with the inner lumen of the sheath. The delivery system also includes an elastic cone with a small aperture in its distal end and a large aperture in its proximal end which receives the distal end of the elongated sheath. In addition, the delivery system includes an intravascular catheter slidably disposed within the delivery sheath. The catheter has an expandable member of the distal extremity thereof, such as an inflatable

balloon, which is adapted to receive an expandable stent on the exterior thereof. The catheter has a first port in its distal end adapted to receive a guidewire and a second port spaced proximally from the distal end of the catheter adapted to receive a guidewire, with both of these ports being in communication with an inner lumen extending within the interior of the catheter. The second guidewire receiving port should be spaced proximally from the expandable member on the distal extremity of the catheter. Means may be provided to adjust the relative axial positions of the catheter and sheath to expose the expandable stent on the expandable member of the catheter so that the stent can be expanded against the blood vessel wall by expanding the expandable member.

Preferably, both the delivery sheath and the intravascular catheter have slits in the walls thereof which extend distally from their proximal ports to facilitate the removal of these devices from the guidewire upon the withdrawal of the delivery system from the patient's vascular system after the delivery of a stent. The distal end of the delivery sheath may also have slits in the walls thereof which extend a short distance proximally from its distal end to facilitate in the relative axial position adjustment of the delivery sheath and intravascular catheter.

In a typical situation, the guidewire used to deliver a dilatation catheter through the patient's vascular system to a stenotic region therein is left disposed within the patient after the dilatation catheter has been removed therefrom. To maintain access to the stenotic region, the distal end of the guidewire should be left crossing the stenotic region where the stent is to be placed. The proximal end of the guidewire, which extends out of the patient, is first inserted through an elastic cone by threading the guidewire into the smaller and out the larger of the two apertures which comprise the cone. Then the guidewire is inserted through the port in the

distal end of the intravascular catheter which has a stent mounted on the expandable member. The intravascular catheter is disposed within the delivery sheath with the distal end of the catheter extending out the port in the distal end of the delivery sheath to facilitate the insertion of the proximal end of the guidewire. The relative axial position between the delivery sheath and intravascular catheter is adjusted so that the expandable member on the distal extremity of the intravascular catheter with the expandable stent mounted thereon is pulled back into the inner lumen of the delivery sheath. The distal end of the delivery sheath is then tucked within the large aperture of the elastic cone. Tucking the delivery sheath within the elastic cone aids the advancement of the stent delivery system through the patient's vascular system by providing the system with a profile suited for making turns through tortuous vessels. The delivery sheath and the catheter therein are then advanced through the patient's vascular system, preferably over a guidewire which extends from outside the patient to the ostium of the desired coronary artery, until the stent mounted on the expandable member of the intravascular catheter is positioned within the stenotic region of the patient's blood vessel.

The relative axial positions of the delivery sheath and the intravascular catheter having the stent thereon is adjusted to urge the distal end of the vascular catheter out of the distal end of the sheath to expose the expandable stent. Either the catheter can be advanced distally with respect to the sheath or the sheath can be withdrawn proximally with respect to the catheter or both movements can be employed. As the relative axial positions are adjusted, the cone disengages from the sheath and collapses upon the distal end of the catheter. Once the stent is completely out of the delivery sheath, the expandable member on the intravascular catheter can be expanded to expand the stent against stenotic mass within

the blood vessel. After expanding the stent, the expandable member on the vascular catheter is contracted so that the catheter can be removed from the patient's blood vessel, leaving the expanded stent in its desired position therein.

The delivery sheath and the intravascular catheter may be withdrawn together or the sheath may be withdrawn first followed by withdrawal of the catheter. The sheath and the catheter can be peeled away from the guidewire with the guidewire sliding through the slits which extend distally from the proximal ports thereof. The exposed section of the guidewire is secured, e.g., manually held, in place so that the sheath and the intravascular catheter can be pulled off the proximal end of the guidewire.

The delivery system of the invention can effectively deliver a stent to a desired location within a patient's blood vessel, it can allow the stent to be secured within the desired location, and it can be easily and quickly removed. These and other advantages of the invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partial longitudinal cross-sectional view of a stent delivery system which embodies features of the invention.

Fig. 2 is a top view of the delivery sheath and elastic cone of the stent delivery system shown in Fig. 1.

Fig. 3 is a transverse cross-sectional view taken along the lines 3-3 shown in Fig. 1.

Fig. 4 is a transverse cross-sectional view taken along the lines 4-4 shown in Fig. 1.

Fig. 5 illustrates a stent mounted on the outer surface of a balloon of the intravascular catheter shown in Fig. 1.

Fig. 6 illustrates the advancement of the stent delivery system shown in Fig. 5 into an artery which has been damaged by an intravascular procedure such as an angioplasty and the location of the elastic cone prior to the relative axial position adjustment of the delivery sheath and intravascular catheter.

Fig. 7 illustrates the inflation of the balloon on the intravascular catheter shown in Fig. 1 which expands the stent mounted on the exterior thereof and the location of the elastic cone after the relative axial position adjustment of the delivery sheath and intravascular catheter.

Fig. 8 illustrates the expanded stent disposed within a damaged arterial section maintaining the patency thereof.

Fig. 9 is a partial cross-sectional view of the manipulator shown in Fig. 1.

Fig. 10 is a perspective view of an alternative manipulator mounted on the proximal end of the delivery system shown in Fig. 1.

Fig. 11 is a plan view of the manipulator shown in Fig. 10.

Fig. 12 is an elevational view, partially in section, of the manipulator shown in Fig. 10.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1-4 illustrate a stent delivery system which embodies features of the invention. Generally, the delivery system includes a delivery sheath 10 which has an outer lumen 11 and an intravascular catheter 12 disposed within the outer lumen 11. The intravascular catheter has an elongated catheter body 13 and a balloon 14 on the distal portion of the catheter body. A manipulating device

15 is provided on the distal end of the delivery system which is employed to effect relative axial or longitudinal movement between the delivery sheath 10 and the intravascular catheter 12. An expandable stent 16, which is to be delivered within a patient's body lumen, is mounted on the exterior of the balloon 14. During the advancement of the stent delivery system through the patient's vascular system to the region of an occlusion, the sheath 10 is tucked within an elastic cone 58. Figure 1 shows the location of the elastic cone 58 after the relative axial positions of the sheath 10 and catheter 12 are adjusted to expose the expandable stent 16.

The delivery sheath 10 has a distal port 17 in its distal end which is in fluid communication with the outer lumen 11 and a proximal port 18 disposed proximally to the distal port. The distal portion of delivery sheath 10 tapers down in a spherical-like manner so that the cross-sectional area is somewhat less in the distal region than the cross-sectional area of the rest of the delivery sheath. A slit 19 extends from the proximal port 18 to a location just proximal to the distal port 17. In one embodiment, a plurality of slits 59 in the wall of sheath 10 extend a short distance from the distal port 17. As contemplated, the slits 59 would facilitate in the relative axial position adjustment of the sheath 10 and intravascular catheter 12.

The intravascular catheter 12 has a distal port 20 and a proximal port 21 which are in fluid communication with a first inner lumen 22 extending within the distal portion of the catheter 12 and being adapted to slidably receive a guidewire therein. A slit 23 extends from the proximal port 21 to a location 24 proximal to the proximal end of balloon 14. The proximal end of the guidewire receiving first inner lumen 22 is provided with a ramp 25 to guide the proximal end of guidewire 26 out the proximal port 21 of intravascular catheter 12 when the catheter is mounted onto the guidewire, as will be discussed

hereinafter. A second, much longer inner lumen 27 is provided within the catheter body 13 to direct inflation fluid from the proximal end of the catheter body to the interior of the balloon 14.

5 Proximal to the proximal port 21 in the catheter body 13 is a stiffening member 28 which is disposed in third inner lumen 29 provided within the catheter body 13. As shown in the drawings, the third inner lumen 29 and the first inner lumen 22 may be the same lumen with a plug 30 separating the two lumens. The ramp 25 is on the distal side of the plug 30.

10 As illustrated in Figs. 1 and 9, the manipulator 15 on the proximal end of the delivery system has a housing 31 with an interior chamber 32, a cap 33 rotatably mounted onto the distal end of the housing 31, an elongated drive member 34 which has male threads on the exterior thereof and which is at least partially disposed within the interior chamber 32 and a Luer lock 35 which is fixed within the proximal end of the housing 31. The proximal end 36 of the sheath 10 is secured to the distal end 37 of the elongated drive member 34 which extends out of the distal end of the housing 31. As shown in more detail in Fig. 9, the proximal end 38 of the catheter body 13 passes through passageway 39 in the elongated drive member 34 and is fixed within the Luer lock 35 by suitable means such as adhesive. The cap 33 which is rotatably mounted onto the distal end of the housing 31 is provided with an inner threaded collar 40 adapted to threadably engage the threaded exterior of the elongated driving member 34. Rotation of the cap 33 moves the driving member 34 axially to thereby effect relative axial movement between the sheath 10 and the intravascular catheter 12. As can be seen from Figs. 1 and 6, the outer lumen 11 is axially spaced from catheter 12, at inner lumen 27, in a substantially non-abutting manner. Thus when the delivery sheath 10 overlies the intravascular catheter 12, there is little or no contact present at the interface between the

outer lumen 27 proximal to the distal end of intravascular catheter 12.

5 In a typical situation, the stent delivery system of the invention is used after an intravascular procedure has damaged a patient's arterial lining to such an extent that the lining needs support to prevent it from collapsing into the arterial passageway and thereby preventing sufficient blood flow through the blood vessel. In these situations there will usually be a guidewire 26 (or other
10 guiding member) in place extending across the damaged section of the artery such as shown in Fig. 6. The proximal end of the guidewire 26, which extends out of the patient during the entire procedure, is inserted through the elastic cone 58 by threading the guidewire 26 into the small aperture 61 and out the large aperture 60 of the
15 cone 58. The guidewire 26 is then inserted through the distal port 20 in the distal end of the catheter 12 and advanced proximally through the first inner lumen 22 until the proximal end of the guidewire impacts the ramp 25 and is thereby directed through the proximal port 21.

20 The intravascular catheter 12 is preferably positioned within the outer lumen 11 of the delivery sheath 10 so that at least a significant portion of the proximal port 18 in the sheath is in alignment with the proximal port 21 of the intravascular catheter. In this manner, proximal advancement of the guidewire 26 through the inner
25 lumen 22 will also direct the proximal end of the guidewire out the proximal port 18 in the delivery sheath 10. The sheath 10 is then tucked within the elastic cone 58 by inserting the distal end of sheath 10 into the proximal end and large aperture 60 of the cone 58. The proximal end of the guidewire 26 may then be manually held to maintain the position of the guidewire within the patient's vasculature, while the stent delivery system is advanced over the
30 guidewire and through the patient's vascular system. The function of the elastic cone 58 is to facilitate the advancement of the stent delivery system. By tucking the

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distal end of sheath 10 within the cone 58 as shown in Fig. 6, the stent delivery system has a profile suited for successfully maneuvering about the sharp turns and angles of the patient's vasculature. The advancement of the stent delivery system continues until the distal ends of the catheter and sheath extend adjacent to or across the damaged arterial site. Next, the manipulator 15 on the proximal end of the delivery system is actuated by rotating the cap 33 on the proximal end of the housing 31 to move the sheath 10 proximally with respect to the catheter 12 and thereby expose the stent 16 mounted on the balloon 14. The elastic cone 58 thereby disengages the sheath 10 and collapses in engagement about the distal portion of the catheter 12 as is shown in Fig. 1. When the balloon and the stent mounted thereon are properly placed within the damaged artery, inflation fluid is directed under substantial pressure through the Luer lock 35 and the inflation lumen 27 in the catheter body 13 to the interior of the balloon 14, expanding the balloon and simultaneously expanding the stent 16 against the blood vessel wall as shown in Fig. 7. The delivery system, both the sheath 10 and the catheter 12, may then be removed from the patient along with the guidewire 26, leaving the expanded stent 16 within the damaged arterial section as shown in Fig. 8 to maintain the patency thereof.

The housing 31 of the manipulator 15 can be held in the palm of the physician's hand, with the thumb and index finger thereof used to rotate cap 33 and thereby cause the necessary relative motion between the sheath 10 and intravascular catheter 12 to expose the stent 16 mounted on the balloon 14. The physician can operate an inflation device, such as described in U.S. Patent 4,439,185, with his or her free hand to inject inflation fluid through Luer lock 35 into the interior of the balloon 14 to inflate the balloon and thereby expand the stent 16 while holding the delivery system in place with the other hand. Upon deflating the balloon 14, the manipulator 15

can again be actuated by the physician rotating cap 33 with the fingers of the hand holding the manipulator 15, to cause relative rotation between the intravascular catheter 12 and the sheath 10, to pull the intravascular catheter 12 back into the distal end of the sheath 10 (or pushing the distal end of the sheath over the distal end of the intravascular catheter 12, depending upon the perspective). The entire assembly, including the guidewire 26, can then be removed from the patient.

The alternative manipulator 50 illustrated in Figs. 10-12 generally includes a housing 51 with an interior chamber 52 and a slidable element 53 with a depending portion 54 which extends through a slot 55 in the wall of the housing and is secured to the proximal end of the sheath 10 which extends through an opening provided in the distal end of the housing. The catheter 12 extends out the proximal end of the sheath 10, out an opening in the proximal end of the housing 51 and into a Luer lock 56 secured to the proximal end of the housing. The proximal end of the catheter 12 is secured within the Luer lock 56 to be in fluid communication with the inner inflation lumen 27 of the catheter so that inflation fluid can be injected through the Luer lock to the interior of the balloon 14 on the catheter to expand the balloon and the stent 16 mounted thereon. As is evident from Fig. 10, movement from element 53 on the exterior of the housing 51 will effect the relative axial movement between the delivery sheath 10 and the catheter 12 required to expose the stent 16 mounted on the balloon 14. The slot 55 has narrowed portions near both ends thereof which have widths just slightly smaller than the depending element 54 so that the position of the slidable element 53 can be locked. The underside of the housing 51 may be provided with undulated surface 57 which is adapted to receive the fingers of an operator to facilitate the gripping thereof.

The dimensions of the intravascular catheter will generally follow the dimensions of intravascular catheters

used in angioplasty procedures in the same arterial location. Typically, the length of a catheter for use in the coronary arteries is about 150 cm, the outer diameter of the catheter shaft is about 0.035 inch (0.89 mm), the length of the balloon is typically about 2 cm and the inflated diameter about 1 to about 8 mm.

The materials of construction may be selected from those used in conventional balloon angioplasty catheters, such as those described in the patents incorporated by reference. The delivery sheath will generally be slightly shorter than the intravascular catheter, e.g., by about the length of the manipulating device 15 or 50, with an inner diameter large enough to accommodate the intravascular catheter and to allow the catheter free longitudinal movement therein. The sheath and the catheter shaft can be made of conventional polyethylene tubing.

While the present invention has been described herein in terms of delivering an expandable stent to a desired location within a patient's blood vessel, the delivery system can be employed to deliver stents to locations within other body lumens such as urethra or Fallopian tubes so that the stents can be expanded to maintain the patency of these body lumens. Various changes and improvements may also be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A kit of parts for the delivery of a stent within a body lumen comprising:

a) an elongated sheath having proximal and distal ends, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter to be disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, an inner lumen which is to receive a guiding member therein and which extends between a first and second ports of the catheter; and

c) means to adjust the relative axial positions of the catheter and the sheath to expose the expandable member so that upon the expansion thereof an expandable stent disposed about the expandable member will thereby be expanded.

2. The stent delivery system kit of claim 1 including an expandable stent which is to be mounted on the exterior of the expandable member on the catheter.

3. The stent delivery system of claim 1, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

4. The stent delivery system of claim 1, wherein the catheter has a wall with a slit therein

extending from the second port to a location proximal to the expandable member.

5. A system for the delivery of an expandable stent within a body lumen over a guiding member comprising:

5 a) an elongated sheath having proximal and distal ends, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

10 b) an elongated catheter disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, and an inner lumen which is to slidably receive a guiding member therein, said inner lumen extending between a first port in the distal end of the catheter and a second port spaced proximally from the distal end of the catheter, both of the ports being in fluid communication with said inner lumen of the catheter, said elongated catheter axially spaced from the outer lumen when said outer lumen overlies said catheter, so as to be substantially non-abutting with said outer lumen at said distal end of the catheter; and

20 c) means to adjust the relative axial positions of the catheter and sheath to expose the expandable member on the catheter.

25 6. The stent delivery system of claim 5, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

7. The stent delivery system of claim 5, wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

8. The stent delivery system of claim 5, wherein the means to adjust the relative axial positions of the catheter and the sheath includes a manipulator comprising:

an elongated housing having proximal and distal ends and an interior chamber;

a cap which has a threaded passageway therethrough and which is rotatably mounted on an end of the elongated housing; and

a longitudinally movable drive member which has a threaded exterior, which is disposed at least partially within the interior chamber of the elongated housing and which has a distal end extending through a central passageway of the cap, rotation of the cap causing axial movement of the drive member.

9. The stent delivery system of claim 8, wherein the longitudinally movable drive member has a central passageway which receives the proximal end of the catheter.

10. The stent delivery system of claim 9, wherein the proximal end of the catheter is fixed to the manipulator housing.

11. The stent delivery system of claim 9, wherein the sheath is fixed to the distal end of the longitudinally movable drive member which extends out the distal end of the manipulator.

12. A method of delivering an expandable stent to a desired location within a patient's body lumen which has a guidewire disposed therein with a proximal end extending out of the patient, the method comprising:

a) providing an elongated sheath having proximal and distal ends, a first port in the distal end of said sheath and a second port spaced proximally from said distal end;

an elongated catheter disposed within said elongated sheath having proximal and distal ends, a first port in the distal end of said elongated catheter and a second port spaced proximally from said distal end of the elongated catheter, said catheter having an expandable member proximally adjacent to said distal end of the catheter and having mounted on the exterior thereof an expandable stent, said catheter having an inner lumen to slidably receive a guidewire therein, said guidewire extending between said first and second ports of the elongated catheter, with said first and second ports of the elongated sheath and first and second ports of the elongated catheter being in fluid communication;

b) adjusting the relative axial positions of the elongated sheath and the catheter so as to at least partially align said second port of the elongated sheath and proximal second port of the elongated catheter;

c) positioning said guidewire so that a portion of the guidewire extends through said second port of the elongated sheath and proximal second port of the elongated catheter;

d) advancing said sheath and catheter over the guidewire through the body lumen to the desired location therein;

e) adjusting the relative axial positions of said sheath with respect to said catheter to expose said expandable stent on said expandable member;

f) expanding said expandable member to thereby expand said stent mounted thereon at said desired location within the body lumen, after said expandable stent has been exposed;

g) contracting said expandable member on the catheter; and

h) withdrawing said catheter and sheath from said body lumen.

13. The method of claim 12, wherein the expandable member is a balloon and wherein inflation fluid is directed to the interior of the balloon to expand the balloon and thereby expand the stent mounted thereon.

14. The method of claim 12, wherein the expandable stent engages the wall defining the body lumen when said stent is expanded so as to maintain the patency thereof.

15. A system for delivery of an expandable stent within a body lumen comprising:

a longitudinally elongated catheter having a proximal end and a distal end,

a guidewire to be slidably received inside said catheter;

said catheter having a balloon portion at its distal end to expand said expandable stent;

an elongated outer lumen, having a proximal and a distal end, surrounding said catheter and to cover said expandable stent, said outer lumen axially spaced from said catheter at said distal end of the catheter, when said outer lumen

15

overlies said catheter, so as to be substantially non-abutting with said catheter at said distal end of the catheter;

means to adjust the relative axial positions of the outer lumen and the catheter to uncover said expandable stent.

16. The stent delivery system of claim 15, wherein said outer lumen has a longitudinally extending slit extending therein, to allow passage of said guidewire.

17. The stent delivery system of claim 15, wherein the means to adjust the relative axial positions of the outer lumen and catheter includes a manipulator comprising:

an elongated housing with proximal and distal ends and an interior chamber;

a cap with a threaded passageway therethrough and rotatably mounted on an end of the elongated housing; and

a longitudinally movable drive member having a threaded exterior, disposed at least partially within the interior chamber of the elongated housing and having a distal end extending through the central passageway of the cap;

whereby rotation of said cap causes axial movement of said drive member.

18. The stent delivery system of claim 17, wherein said longitudinally movable drive member has a central passageway operatively connected to said proximal end of said outer lumen.

19. The stent delivery catheter of claim 18, wherein said proximal end of the catheter is fixed to the manipulator housing.

20. The stent delivery catheter of claim 18, wherein the proximal end of said outer lumen is fixed to the distal end of the longitudinally movable drive member.

21. A kit of parts for the delivery of a stent within a body lumen comprising:

a) an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter to be disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, an inner lumen which is to receive a guiding member therein and which extends between a first and second ports of the catheter; and

c) an elastic cone having proximal and distal ends, having a small aperture in the distal end and a large aperture in the proximal end thereof, the large aperture of which is to receive the distal end of the elongated sheath;

d) means to adjust the relative axial positions of the catheter and the sheath to expose the expandable member so that upon the expansion thereof an expandable stent disposed

about the expandable member will thereby be expanded.

22. The stent delivery system kit of claim 21 including an expandable stent which is to be mounted on the exterior of the expandable member on the catheter.

23. The stent delivery system of claim 21, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

24. The stent delivery system of claim 21, wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

25. A system for the delivery of an expandable stent within a body lumen over a guiding member comprising:

a) an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, and an inner lumen which is to slidably receive a guiding member therein, said inner lumen extending between a first port in the distal end of the catheter and a second port spaced proximally from the distal end of the

catheter, both of the ports being in fluid communication with said inner lumen of the catheter, said elongated catheter axially spaced from the outer lumen when said outer lumen overlies said catheter, so as to be substantially non-abutting with said outer lumen at said distal end of the catheter; and

c) an elastic cone having proximal and distal ends, having a small aperture in the distal end and a large aperture in the proximal end thereof, the large aperture of which is to receive the distal end of the elongated sheath;

d) means to adjust the relative axial positions of the catheter and sheath to expose the expandable member on the catheter.

26. The stent delivery system of claim 25, wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

27. The stent delivery system of claim 25, wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

28. The stent delivery system of claim 25, wherein the means to adjust the relative axial positions of the catheter and the sheath includes a manipulator comprising:

an elongated housing having proximal and distal ends and an interior chamber;

a cap which has a threaded passageway therethrough and which is rotatably mounted on an end of the elongated housing; and

a longitudinally movable drive member which has a threaded exterior, which is disposed at least partially within the interior chamber of

the elongated housing and which has a distal end extending through a central passageway of the cap, rotation of the cap causing axial movement of the drive member.

29. The stent delivery system of claim 28, wherein the longitudinally movable drive member has a central passageway which receives the proximal end of the catheter.

30. The stent delivery system of claim 29, wherein the proximal end of the catheter is fixed to the manipulator housing.

31. The stent delivery system of claim 29, wherein the sheath is fixed to the distal end of the longitudinally movable drive member which extends out the distal end of the manipulator.

32. A method of delivering an expandable stent to a desired location within a patient's body lumen which has a guidewire disposed therein with a proximal end extending out of the patient, the method comprising:

a) providing an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, a first port in the distal end of said sheath and a second port spaced proximally from said distal end;

an elongated catheter disposed within said elongated sheath having proximal and distal ends, a first port in the distal end of said elongated catheter and a second port spaced proximally from said distal end of the elongated catheter, said catheter having an expandable member proximally adjacent to said distal end of the catheter and having mounted on the exterior

thereof an expandable stent, said catheter having an inner lumen to slidably receive a guidewire therein, said guidewire extending between said first and second ports of the elongated catheter, with said first and second ports of the elongated sheath and first and second ports of the elongated catheter being in fluid communication;

an elastic cone having proximal and distal ends, having a small aperture in the distal end and a large aperture in the proximal end thereof, the large aperture of which is the receive the distal end of the elongated sheath;

b) adjusting the relative axial positions of the elongated sheath and the catheter so as to at least partially align said second port of the elongated sheath and proximal second port of the elongated catheter;

c) positioning said guidewire so that a portion of the guidewire extends through said second port of the elongated sheath, the small aperture of the elastic cone and proximal second port of the elongated catheter;

d) advancing said sheath and catheter over the guidewire through the body lumen to the desired location therein;

e) adjusting the relative axial positions of said sheath with respect to said catheter to expose said expandable stent on said expandable member thereby disengaging said elastic cone from said sheath;

f) said elastic cone collapsing upon distal end of the catheter;

g) expanding said expandable member to thereby expand said stent mounted thereon at said desired location within the body lumen, after said expandable stent has been exposed;

h) contracting said expandable member on the catheter; and

i) withdrawing said catheter and sheath from said body lumen.

33. The method of claim 32, wherein the expandable member is a balloon and wherein inflation fluid is directed to the interior of the balloon to expand the balloon and thereby expand the stent mounted thereon.

34. The method of claim 32, wherein the expandable stent engages the wall defining the body lumen when said stent is expanded so as to maintain the patency thereof.

35. A system for the delivery of an expandable stent within a body lumen over a guiding member comprising:

a) an elongated sheath having proximal and distal ends, a tapering portion proximal to said distal end, a plurality of slits extending a short distance from said distal end, an outer lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the outer lumen;

b) an elongated catheter disposed within the outer lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is to receive on the exterior thereof an expandable stent, and an inner lumen which is to slidably receive a guiding member therein, said inner lumen extending between a first port in the distal end of the catheter and a second port spaced proximally from the distal end of the

catheter, both of the ports being in fluid communication with said inner lumen of the catheter, said elongated catheter axially spaced from the outer lumen when said outer lumen overlies said catheter, so as to be substantially non-abutting with said outer lumen at said distal end of the catheter; and

c) an elastic cone having proximal and distal ends, having a small aperture in the distal end and a large aperture in the proximal end thereof, the large aperture of which is the receive the distal end of the elongated sheath;

d) means to adjust the relative axial positions of the catheter and sheath to expose the expandable member on the catheter.

ABSTRACT OF THE DISCLOSURE

The invention is directed to a stent delivery method and system which generally includes an elongated delivery sheath and a catheter disposed within an outer lumen of the sheath having an expandable member on its distal extremity. An expandable stent is mounted on the expandable member of the catheter. The distal portion of the sheath tapers down and is tucked within an elastic cone during transport of the stent to a stenotic region. A manipulating device is provided on the proximal end of the delivery system to effect relative axial movement between the sheath and the catheter so as to expose the stent mounted on the expandable member on the catheter within a body lumen such as a coronary artery and allow the expansion of the stent by the expansion of the expandable member. The elastic cone thereby disengages from the sheath and collapses about the distal end of the catheter. The delivery sheath has a first port in its distal end and a second port in the sheath wall proximally disposed from the distal end of the sheath. The catheter likewise has a first port in its distal end and a second port proximally disposed from the distal end of the catheter. An inner lumen extends within the distal portion of the catheter between the first and second ports and slidably receives a guiding member such as a guidewire. This system allows the stent to be delivered over a guidewire previously advanced to the desired location within a body lumen.

Fig. 1

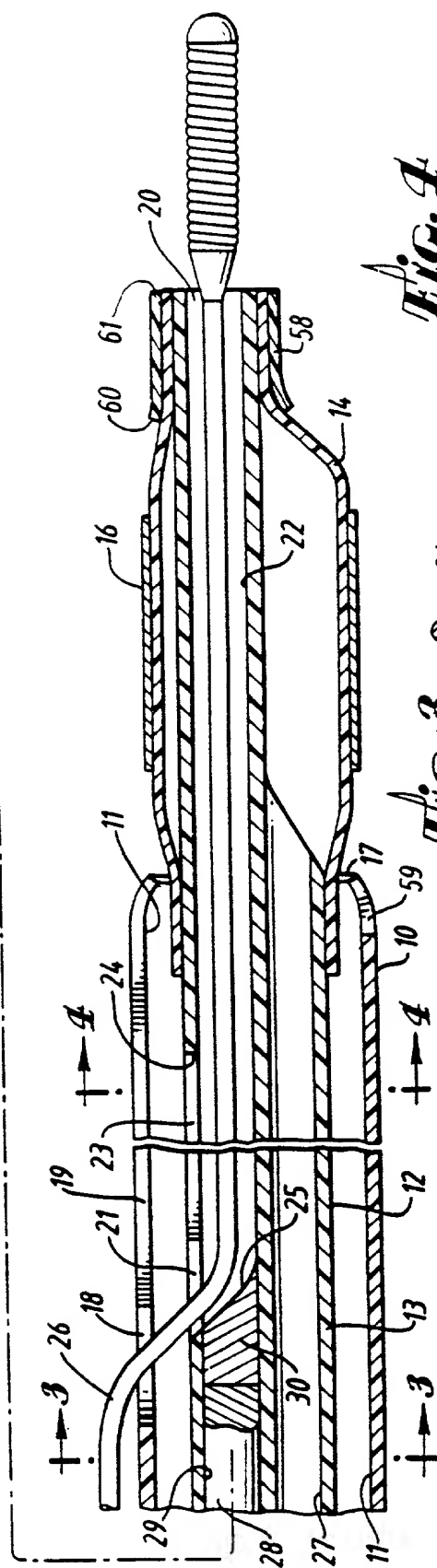
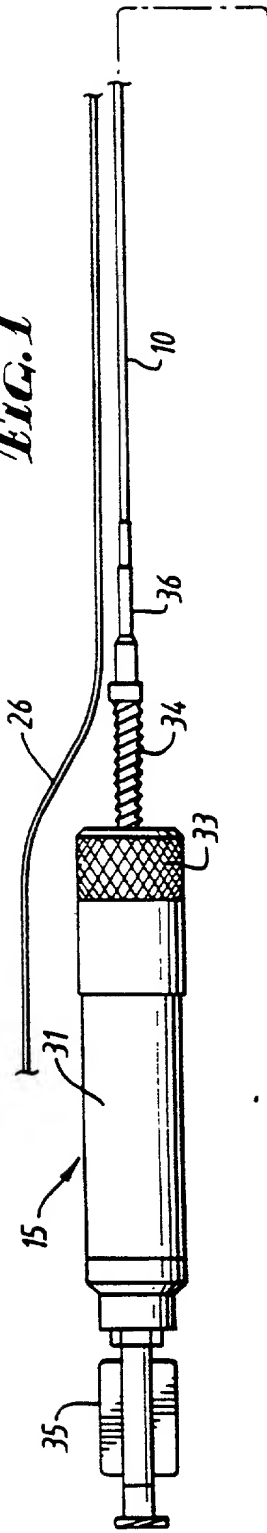


Fig. 4

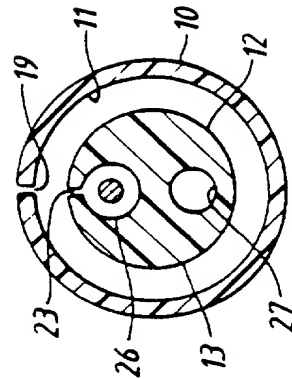


Fig. 3

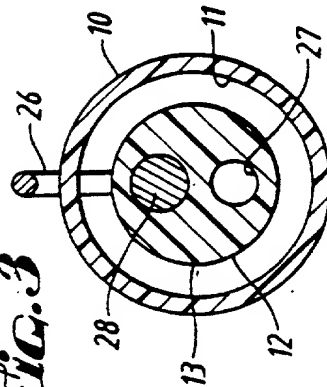


Fig. 2

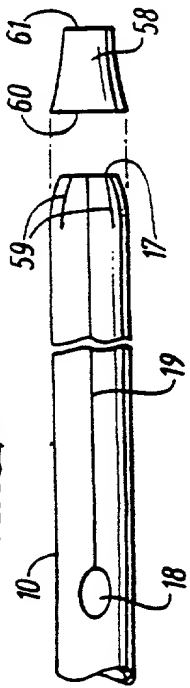


FIG. 5

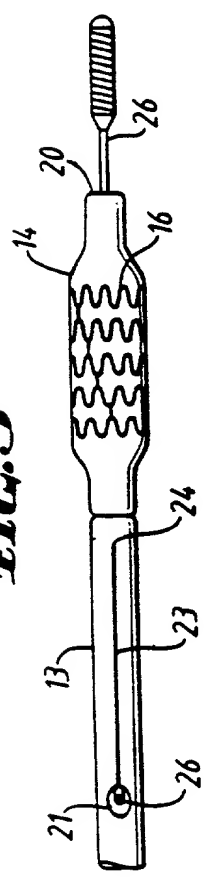


FIG. 6

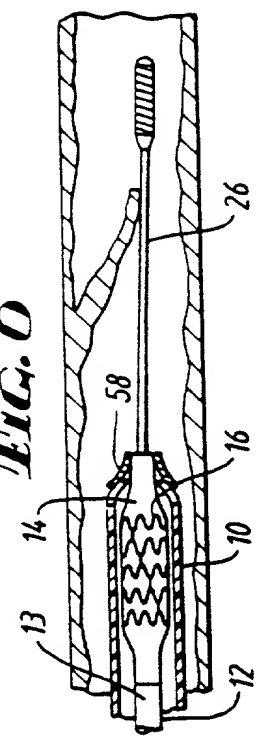


FIG. 7

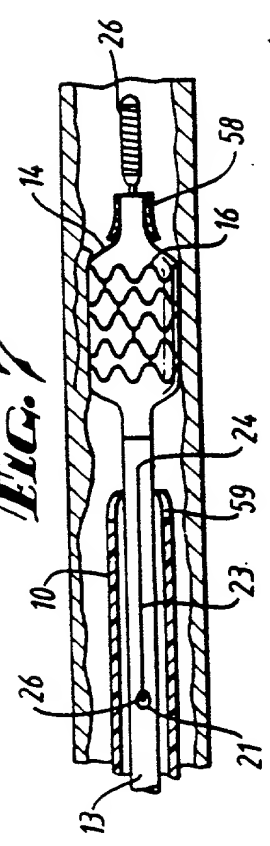


FIG. 8

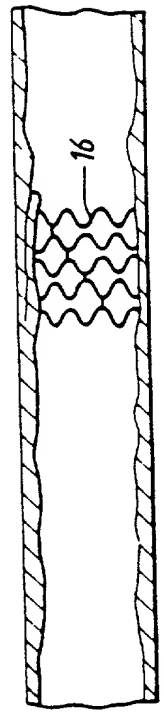
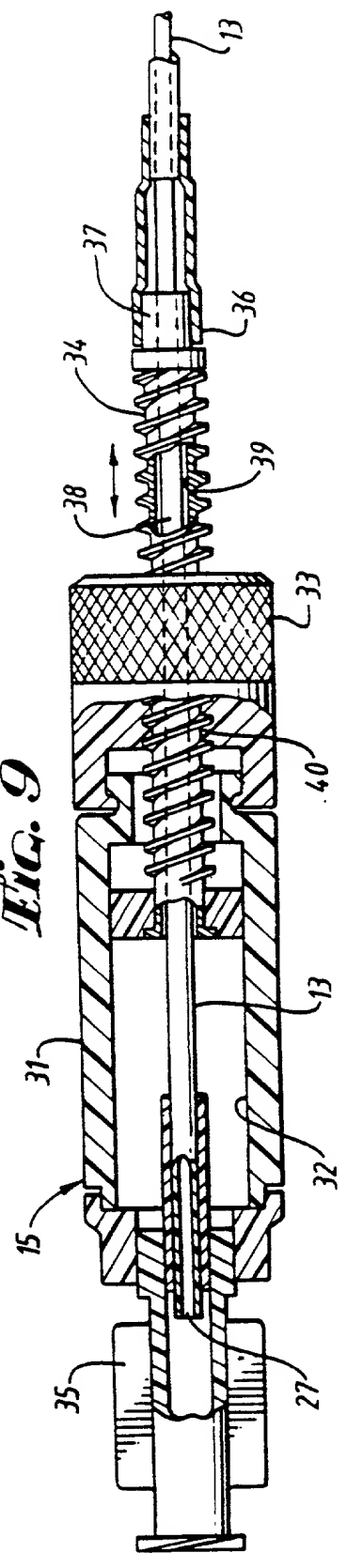
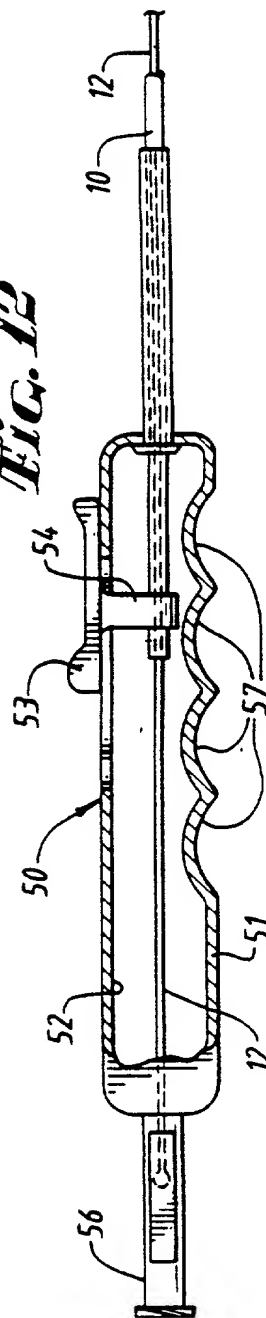


FIG. 9





DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

As the below named inventors, we hereby declare that:

Our residences, post office addresses and citizenships are as stated below next to our names;

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled STENT DELIVERY SYSTEM the specification of which (check one)

 is attached hereto
 X was filed on July 6, 1993
Application Serial No. 08/085,959

and is amended through a preliminary amendment (attached hereto) to correct the inventorship of the invention.

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

This application in part discloses and claims subject matter disclosed in the earlier filed pending application, Serial No. 07/647,464 filed January 28, 1991.

We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Sec. 1.56(a).

We hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

<u>None</u>				
Number	Country	Day/Month/Year filed	Yes	No

We hereby claim the benefit under Title 35, United States Code, Sec. 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Sec. 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

<u>07/647,464</u>	<u>January 28, 1991</u>	<u>Pending</u>
Appln. Serial No.	Filing Date	Status

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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Inventor's signature: Lilip Lau

Date: Oct. 31, 1993

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Full name of second inventor: William M. Hartigan

Inventor's signature: _____

Date: _____, 1993

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Citizenship: United States of America

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Fremont, California 94536

Full name of third inventor: Farhad Khosravi

Inventor's signature: _____

Date: _____, 1993

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Full name of fourth inventor: Kurt R. Klemm

Inventor's signature: _____

Date: _____, 1993

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Citizenship: United States of America

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Full name of fifth inventor: Ulrich Sigwart

Inventor's signature: _____

Date: _____, 1993

Residence: Morges, Switzerland

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Post Office Address: Chemin des Pétoleyres 28
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DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

As the below named inventors, we hereby declare that:

Our residences, post office addresses and citizenships are as stated below next to our names;

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled STENT DELIVERY SYSTEM the specification of which (check one)

_____ is attached hereto

X was filed on July 6, 1993

Application Serial No. 08/085,959

and is amended through a preliminary amendment (attached hereto) to correct the inventorship of the invention.

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

This application in part discloses and claims subject matter disclosed in the earlier filed pending application, Serial No. 07/647,464 filed January 28, 1991.

We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Sec. 1.56(a).

We hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

<u>None</u>				
Number	Country	Day/Month/Year filed	Yes	No

We hereby claim the benefit under Title 35, United States Code, Sec. 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Sec. 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

<u>07/647,464</u>	<u>January 28, 1991</u>	<u>Pending</u>
Appln. Serial No.	Filing Date	Status

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

RICHARD A. BARDIN, Registration No. 20,365, GILBERT G. KOVELMAN, Registration No. 19,552, JOHN S. NAGY, Registration No. 30,664, and KAMRAN FATTAHI, Registration No. 35,758. Direct all telephone calls to JOHN S. NAGY, at telephone No. (310) 824-5555.

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Full name of third inventor: Farhad Khosravi

Inventor's signature: _____

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Full name of fourth inventor: Kurt R. Klemm

Inventor's signature: _____

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